



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/693,115

10/24/2003

Ross Tsukashima

70826.01

1645

22509 7590 04/09/2007  
MICHAEL E. KLICPERA  
PO BOX 573  
LA JOLLA, CA 92038-0573

EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

04/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/693,115

Applicant(s)

TSUKASHIMA ET AL

Examiner

Robert L. Nasser

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13, 15-23 and 25-31 is/are rejected.
- 7) ☒ Claim(s) 4, 14, 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/6/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim positively recites a collecting pool. However, the only mention of a collecting pool is a pool of condensate that is formed. This means that the device does not always have the collecting pool and therefore there is no written description of the device having the pool. Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 11, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 15 are rejected in that the scope of the claim cannot be determined since there is no antecedent basis for the sample of liquefied breath. Claim 11 is rejected in that it states that the medical

condition is a single condition, but the claim states that it renders various diagnoses.

This seems contradictory.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, 2, 4, 5, 8, 9, 10, 11, 12, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Mault 2003/0023181. Mault teaches an apparatus that condenses a sample of breath on a fluorescent film (see paragraph [0048])). The examiner notes that the paragraph states that the condensation is reduced. However, a reduction in condensation still leaves some condensation. In addition, Mault has a sensor 34 in close proximity to the film, a processing receiver that is in real time communication with the detector via leads or wires 34a. The examiner notes that claim 1 does not state that the sensor is in contact with condensate formed on the sensor or that the sensor measures a species present in the condensate. As such, Mault anticipates the claim. Claim 2 is rejected in that the device directs the breath towards the film. Claim 4 is rejected in that in paragraph [0086], Mault teaches that it can be used to diagnose

asthma. Claims 8 is rejected in that Mault controls the film temperature, which therefore controls the condensate temperature. Claims 9, 10, 11, 12, and 16 are rejected for the reasons given above, noting that paragraph [0086] teaches that various diagnoses can be made. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault '181 in view of Mault 2003/0208133. With respect to claims 6 and 13, in paragraph 24, Mault'133 teaches that it is known to have a breath sensor wirelessly communicate with the processor. Hence, it would have been obvious to modify Mault '181 to have the sensor and processor wirelessly communicate, as it is merely the substitution of one known communication technique for another.

Claim 17-20, and 22, are rejected under 35 USC 103(a) as being unpatentable over Mault '181 in view of Gustaffson 5447165. Mault '181 has all of the features of claim 17, except that it does not have the processor in communication with a treatment device. Gustaffson teaches such communication to enable quicker treatment adjustment for the patient, to provide more immediate relief of the patient's condition. As such, it would have been obvious to modify Mault '181 to provide such communication, in order to provide quicker relief to the patient. Claims 18-20, 22, 24,

29, and 30 are rejected for the reasons given above. Claim 25 is rejected in that since Gustaffson administers agent to treat asthma, it treats an acidic condition.

Claims 21 and 23 are rejected under 35 USC 103(a) as being unpatentable over Mault '181 in view of Gustaffson, as applied to claims 17-20, and 22 above, further in view of Mault '133. Mault teaches that it is known to have a breath sensor wirelessly communicate with the processor. Hence, it would have been obvious to modify Hunt et al to have the sensor and processor wirelessly communicate, as it is merely the substitution of one known communication technique for another.

Claims 25 and 26 are rejected under 35 USC 103(a) as being unpatentable over Mault '181 in view of Gustaffson, as applied to claims 17-20, and 22 above, further in view of applicant's admission. In the parent application, 10/413701, in the response filed 9/15/2005, applicant did not challenge the examiner's official notice that it is known to treat asthma with sodium biocarbonate. It would have been obvious to modify the combination to use sodium biocarbonate as the treating agent, as it is merely the substitution of one known equivalent treatment agent for another.

Claims 27 and 28 are rejected under 35 USC 103(a) as being unpatentable over Mault '181 in view of Gustaffson, as applied to claims 17-20 and 22 above, further in view of Roberts et al 5388571. Roberts et al teaches a treatment system that includes both a CPAP machine and a nebulizer for treating respiratory conditions. As such, it would have been obvious to modify the above combination to adjust both the CPAP treatment and the medicament treatment, as it is merely the substitution of one known treatment for another.

Claims 4, 14, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 4, 14, and 24 are rejected in that none of the art has a pH sensor in close proximity to a film on which a sample of condensate is formed by the device.

Claims 7, 15, and 29-31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claims 7 and 15 define over the art in that none of the art has the means to circulate the breath, as recited. Claims 29-31 define over the art in that none of the art has the sensor immersed in a pool of collected breath condensate, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser  
Primary Examiner  
Art Unit 3735

RLN  
April 1, 2007

